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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,740	04/18/2000	Anthony Murray	5697.200-US	2226

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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/551,740	<b>Applicant(s)</b> MURRAY ET AL.	
	<b>Examiner</b> Binta M. Robinson	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-5, 15, 16, 31, 32, 38-42 and 48-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-5, 15, 16, 31, 32 and 38-42 is/are rejected.

7) ☒ Claim(s) 48-53 is/are objected to.

8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other:  |

### Detailed Action

(new rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 15-16, 25-28, 31-32, 38-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for A1, A2 equal to all saturated, unsaturated or aromatic 5-6 membered cyclic ring systems containing one or more carbon atoms and optionally from one to four heteroatoms selected from N, O, or S, Ar equal to all heteroarylenes M equal to all heterocyclcyl, heteroaryl, or heteroarylalkyl groups, wherein heterocyclcyl is a saturated or unsaturated non-aromatic group having 5 or 6 ring atoms containing one to four carbon atoms and one to four heteroatoms selected from N, O, or S, where Heteroaryl is a 5 to 6 membered monocyclic or a 9 to 10 membered bicyclic aromatic system containing one or more heteroatoms selected from N, O or S encompassed in formula I in claim 1 on pages 2-3 of the application for reasons of record at paper no. 11/B. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of the claims fails to meet the requirements of enablement and

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directional guidance. There is no reasonable showing that such diverse compounds will have all of the alleged properties.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Douche* 169 USPQ 429 coca, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, A1 and A2 encompass a vast Markush grouping of moieties other than the phenyl and furyl rings, exemplified. In terms of the nature of the invention which is the second Wands factor, these compounds are useful in treating conditions mediated by the peroxisome proliferator-

activated receptors. In terms of the fifth Wands factor, the level of predictability in the art is low, because there are no examples of these compounds effect on nuclear receptor activity. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not show test results for these compounds effect on nuclear receptor activity. In terms of the 8<sup>th</sup> Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 15-16, 25-28, 31-32, 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 1, page 2, the phrase "5-6 membered cyclic ring", in lines 4-5, the terms "heterocyclyl", "heteroaryl", "heteroarylalkyl", "heteroaryloxy", "heteroarylalkoxy", and in line 22, the term "arylene" or "heterarylene" and all other occurrences in claims 2-5, 15-16, 25-28, 31-32, 38-42, is indefinite. These terms are so broad as to render this claim meaningless. For example, what "heterocyclyl" ring is the applicant claiming? These terms are indefinite in all occurrences throughout the application.

(new objection)

Claims 48-53 are objected to because they are based on a rejected claim.

### **Response to Applicant's Remarks**

#### **112, first paragraph rejection**

The applicant asserts that the compounds are enabled because representative examples of the compounds are disclosed in the application with their reaction pathways. The applicant also asserts that the specification also includes guidance to one skilled in the art as to how to use the compounds in various pharmaceutical compositions. The applicant also asserts that guidance is given as to how one skilled in the art would test the effectiveness of the compounds as inhibitors of PPAR alpha and alpha, or as to how to use the compounds in various pharmaceutical compositions.

However, the examiner notes that several of the Wands factors are not fulfilled. A1 and A2 moieties of the compound equal only to furyl or phenyl is not fairly representative of the breadth of the A1, and A2 radicals in the compound. The amount of direction provided by the inventor is poor, because the applicant does not show test results of these compounds activity as inhibitors of PPAR alpha and alpha. In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification. As stated before, no results of

tests for specific examples were included in the specification for their affect on PPAR alpha and alpha activity.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7<sup>th</sup> and 8<sup>th</sup> wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification , an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on PPAR alpha and alpha activity.

In terms of the 8<sup>th</sup> Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

#### **112, second paragraph Rejection**

The applicant alleges that the phrases in claim 1, line 1, page 2, "5-6 membered cyclic ring", in lines 4-5, the terms "heterocyclyl", "heteroaryl", "heteroarylalkyl", "heteroarylloxy", "heteroarylalkoxy", and in line 22, the term "arylene" or "heterarylene" and all other occurrences in claims 2-5, 15-16, 25-28, 31-32, 38-42,

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are enabled. The applicant, however, amended the definition to be "a saturated, unsaturated or aromatic 5-6 membered cyclic ring system containing one or more carbon atoms and optionally from one to four heteroatoms selected from N, O, or S." However, the examiner notes that this phrase is still indefinite for failing to distinctly claim the invention for the following reasons: For example, heteroaryl rings include rings yet to be discovered or synthesized. For example, 4 oxygen atoms or S atoms in 1 ring have not been made – in addition it would include O, S, or N with at least one carbon atom without the appropriate configuration. It doesn't stop there. Heteroaryl could include diffusion of additional heterocyclic ring systems or alternatively, the fusion with aromatic rings systems ranging from two rings on up to infinity – the problem is exacerbated when an alkyl group is attached thereto.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-223.

Binta Robinson



April 5, 2002



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